IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA
CLARKSBURG DIVISION

REGENERON PHARMACEUTICALS, INC., Plaintiff, v. MYLAN PHARMACEUTICALS INC., Defendant.	Case No. 1:22-cv-00061-TSK **JURY TRIAL DEMANDED**

REGENERON'S RESPONSE TO MYLAN'S POST-HEARING SUPPLEMENT

Regeneron supplies this brief response to Mylan's "Post-Hearing Supplement," filed following the Court's September 29, 2022 scheduling conference. Though Mylan was forced to acknowledge that the BPCIA governs this proceeding, Mylan's submission again provides no response regarding the statutory remedy provided for by the BPCIA in 35 U.S.C. § 271(e)(4)(D), other than to ignore it and hope the Court enters a late trial date to render it a dead letter. That statutory relief is an important component of the bargain that Congress struck in creating a path for biosimilars to rely on innovators' clinical data and develop products through an abbreviated pathway.

The Court has ample case management tools to fashion a schedule that will allow Regeneron to avail itself of that statutory relief, including through phased trial proceedings or otherwise. *E.g.*, Fed. R. Civ. P. 42(b); 54(b). Regeneron also has made clear that it is prepared to take steps that will render the schedule feasible, such as committing to voluntary, early document production and limiting the number of patents for trial. *See* ECF 7 (Motion for Expedited Status Conference), 75 (Rule 26(f) Report). And, in an effort to accommodate Mylan's request for greater certainty, Regeneron also offered not to seek injunctive relief against

the U.S. marketing or sales of Mylan's current aBLA product (BLA No. 761274) on the patents asserted in the Complaint but not tried during the first stage of litigation. That is a concrete proposal, not a "vague[]" suggestion, as Mylan asserts. It is a way to give Mylan the certainty it professes to seek and avoid the concern it raised repeatedly (ECF 26 at 3, 5, 9) regarding these patents interfering with Mylan's commercialization. As a practical matter, given that Regeneron has agreed that it will not seek injunctive relief in connection with the patents not initially litigated against the U.S. marketing or sales of Mylan's current aBLA product (BLA No. 761274), it is unlikely that the second phase will proceed at all in the event that Regeneron prevails as to any of the patents asserted in the first phase.

So that its proposal is not subject to mischaracterization as "vague," Regeneron attaches a proposed order that would effectuate Regeneron's proposal, which provides:

(1) Three days after the Scheduling Order setting the case for a June 2023 trial, Regeneron will identify 6 patents from 3 patent families to proceed in the first stage of litigation;

(2) That same day, Regeneron will also stipulate that it will not seek injunctive relief against the U.S. marketing or sales of Mylan's current aBLA product (BLA No. 761274) on the other 18 patents asserted in the Complaint;

(3) Upon the later of (a) seven days after the Court's *Markman* order or (b) seven days after the close of fact discovery, Regeneron will further narrow the first-stage litigation to three patents and a maximum of 25 claims.

Mylan rejects even this framework, arguing that Regeneron could still seek damages for infringement on the second-phase patents in the event Mylan launches. ECF 77 at 1-2. *But that would be the case even under Mylan's proposed schedule*. Specifically, Mylan has proposed to

litigate all 24 patents at a trial two years from now, in September 2024, well after the time when Mylan's product presumably will be approved and when Mylan may launch. ECF 75-2, "Proposal 1." And under that scenario, Mylan would face the uncertain prospect of *both* injunctive relief *and damages* with respect to all 24 of the asserted patents. Regeneron's proposal, in contrast, would give Regeneron the opportunity to obtain statutory relief under § 271(e)(4)(D) on the first-stage patents while giving Mylan certainty against injunctive relief on the second-stage patents with respect to the U.S. marketing or sales of its current aBLA product. Even in the highly unlikely event that all 18 of the other patents were litigated in a second phase, there is no reason that litigation could not also proceed to trial by late 2024—that is, when Mylan has proposed it should take place anyway under its first proposed schedule. It could not be clearer that, notwithstanding its professed need to avoid any risk of damages, Mylan's true objective is to achieve by scheduling procedure what it cannot achieve on the merits: depriving Regeneron of a statutory injunction.

Regeneron thanks the Court for its attention to this matter, and respectfully requests entry of the proposed scheduling order attached to this Response.

Date: September 29, 2022

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CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2022, I electronically filed the foregoing with the Clerk of the Court by using the Court's CM/ECF system. Counsel of record for all parties will be served by the Court's CM/ECF system.

/s/ Steven R. Ruby
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